REMARKS

Applicants appreciate the thorough and detailed examination of the present application as evidenced by the Office Action dated January 12, 2006 (hereinafter, the "Office Action"). The concerns raised by the Examiner are addressed below as set forth in the Office Action.

I. Specification

Applicants submit a new title that is further indicative of the subject matter to which the claims are directed, as suggested by the Examiner.

II. Information Disclosure Statement

The Office Action states that "[t]he information disclosure statement filed 20 July 2004[1] fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The foreign and non-patent literature references were not located in the instant file nor any parent file." Office Action, page 2.

The Manual of Patent Examining Procedure (M.P.E.P.) states the following:

> The examiner will consider information which has been considered by the Office in a parent application when examining (A) a continuation application filed under **37 CFR 1.53(b)** ** (B) a divisional application filed under **37 CFR 1.53(b)** ** or (C) a continuation-in-part application filed under **37 CFR 1.53(b)**. A listing of the information need not be resubmitted in the continuing application unless the applicant desires the information to be printed on the patent.

M.P.E.P. §609.02(A)(2).

Applicants note that the information disclosure statement (IDS) submitted by Applicants included a copy of a form PTO-1449 as filed in parent U.S. Patent Application Serial No. 10/434,259 with the Attorney Docket Number of the parent application struck through and the Attorney Docket number of the present application written thereon. Applicants further note that the references cited in the IDS filed in the present application

[1] Applicants submitted the information disclosure statement on January 30, 2004 at the time of filing the present application.

appear on the face of the issued patent for the parent application, U.S. Patent No. 6,667,321. *See* attached pages 1-3 of the '321 patent. Accordingly, it is Applicants' belief that the USPTO has previously received and/or reviewed the references cited in the IDS, and Applicants are now entitled to have the references considered, and in the event of allowance, listed on a patent issuing from the present application. Applicants are willing to resubmit the references; however, in contrast to the statements set forth in the Office Action, Applicants believe that the date of submission should be considered the original date of submission and not the date of re-submission.

The Office Action further states that "the listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98 and 37 CFR 1.98(a)(2) . . . Therefore, the references cited in the Search Report have not been considered." Office Action, page 3. In addition to citing the Search Report accompanying the Norwegian Office Action, Applicants also separately listed the references cited therein in the IDS. The Examiner has initialed and signed the form PTO-1449, which lists these references. Thus, it is Applicants' belief that the references cited in the Search Report have been considered.

Lastly, Applicants respectfully request the return of a copy of an initialed and signed form PTO-1449 submitted by the Applicants on December 21, 2004.

Should there be any unresolved issues regarding the information disclosure statements submitted by the Applicants as discussed above, Applicants respectfully request that the Examiner contact the Applicants' undersigned representative using the contact information provided herein. The Examiner's consideration of the aforementioned issue is greatly appreciated.

III. Claim Rejections Under 35 U.S.C. §112

Claims 65, 68, 70, 73, 75, 78 and 83 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. *See* Office Action, page 4. In particular, the Office Action states that "[t]he term 'about' in the phrases 'about 5mg to about 60mg' (claim 65) and 'about 10 mg' (claim 68), for example, are relative terms which render the claims indefinite. Since the term 'about' is not defined by the claims and the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention." Office Action, page 4. Applicants respectfully

disagree. Applicants respectfully submit that the term "about" is not indefinite as recited in the present claims.

The term "about" used to define the area of the lower end of a mold as between 25 to about 45% of the mold entrance was held to be clear, but flexible. *See* M.P.E.P. §2173.05(b) (citing *Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968)). Similarly, the Federal Circuit held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch. *See* M.P.E.P. §2173.05(b) (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)). The Federal Circuit, however, held that claims reciting "at least about" were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

Claims 65, 68, 70, 73, 75 78 and 83 recite "about" and not "at least about." Moreover, adequate measuring apparatuses are available to those of ordinary skill in the art so that such artisans would understand what is presently claimed.

Accordingly, Applicants respectfully submit that Claims 65, 68, 70, 73, 75 78 and 83 are not indefinite for at least these reasons, and Applicants respectfully request that these claim rejections be withdrawn.

IV. Claims Rejections Under 35 U.S.C. § 102

Claims 65-84 stand rejected under 35 U.S.C. §102(b) as being anticipated by WO 95/32957 to Astra Aktiebolag (hereinafter, "Astra Aktiebolag"). *See* Office Action, page 5.

It is well accepted that "[a]nticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention." *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000) (*relying on Electro Med. Sys. S.A. v. Cooper Life Scis.*, 32 USPQ2d 1017, 1019 (Fed Cir. 1994). A finding of anticipation further requires that there must be no difference between the claimed invention and the disclosure of the cited reference as viewed by one of ordinary skill in the art. *See Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Additionally, the cited prior art reference must be

enabling, thereby placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 U.S.P.Q. 245, 249 (C.C.P.A. 1964).

Claim 65 recites as follows:

> A pharmaceutical formulation in unit dosage form comprising per dose unit an amount of active ingredient within the range from about 5 mg to about 60 mg of 6-methoxy-2-[[(S)-(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole, **in pure form**, or pharmaceutically acceptable salts, solvates, hydrates, or combinations thereof, wherein said formulation in unit dosage form being adapted for oral administration in the form of a capsule or tablet.

As noted in the specification, in pure form refers to 6-methoxy-2-[[(S)-(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole "present in amounts generally below limits detectable by conventional technology." Present Application, page 18, lines 12-13.

Astra Aktiebolag does not recite a pharmaceutical formulation as recited in Claim 65. In particular, Astra Aktiebolag discusses ethyl carbonate derivatives (e.g. ethoxycarbonyloxymethyl derivatives) of omeprazole. *See* Astra Aktiebolag, page 4, lines 16-31, among other places. Thus, Astra Aktiebolag does not teach or suggest the claimed invention and further fails to adequately describe the claimed invention so that a person of ordinary skill in the art could make and use the present invention.

V. Nonstatutory Double Patenting Rejection

Claims 65-84 stand rejected on the ground of nonstatutory double patenting over the following:

1. Claims 1-68 of U.S. Patent No. 6,369,087;
2. Claims 1-12 of U.S. Patent No. 6,262,085;
3. Claims 1-30 of U.S. Patent No. 6,667,321;
4. Claims 1-24 of U.S. Patent No. 6,444,689;
5. Claims 1-5 of U.S. Patent No. 6,667, 324; and
6. Claims 1-45 of U.S. Patent No. 6,653,329.

See Office Action, pages 5-9.

In an effort to advance prosecution of this application to allowance, Applicants intend to submit a terminal disclaimer upon indication that the pending claims are allowed. Applicants' offer to submit the terminal disclaimer should not be construed as an admission

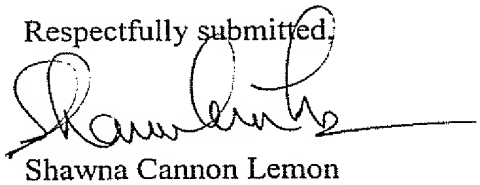
with respect to the nonstatutory double patenting rejections or the Examiner's characterization of Applicants' cited patents as set forth in the Office Action.

Claims 65-84 stand provisionally rejected on the ground of nonstatutory double patenting over Claims 1-101 of copending U.S. Patent Application Serial No. 10/855,809. Applicants respectfully submit that since the claims of the '809 application have not issued, Applicants do not believe that it is necessary to file a terminal disclaimer with this response. However, Applicants are prepared to provide a terminal disclaimer if it is determined to be necessary upon allowance of the relevant claims. Accordingly, Applicants respectfully request that the provisional rejection of Claims 65-84 be withdrawn.

Conclusion

At least in view of the foregoing amendments and remarks, Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,



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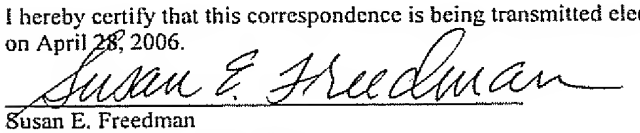

Susan E. Freedman
Date of Signature: April 28, 2006

US006667321B2

(12) **United States Patent**
Whittle et al.

(10) **Patent No.: US 6,667,321 B2**
(45) **Date of Patent: *Dec. 23, 2003**

(54) **ALKOXY SUBSTITUTED BENZIMIDAZOLE COMPOUNDS, PHARMACEUTICAL PREPARATIONS CONTAINING THE SAME, AND METHODS OF USING THE SAME**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 19 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/189,659**

(22) Filed: **Jul. 3, 2002**

(65) **Prior Publication Data**

US 2003/0096845 A1 May 22, 2003

Related U.S. Application Data

(63) Continuation of application No. 10/057,659, filed on Jan. 25, 2002, now Pat. No. 6,444,689, which is a continuation of application No. 09/645,145, filed on Aug. 24, 2000, now Pat. No. 6,369,087, which is a continuation-in-part of application No. 09/519,976, filed on Mar. 7, 2000, now Pat. No. 6,262,085.

(60) Provisional application No. 60/150,878, filed on Aug. 26, 1999.

(51) **Int. Cl.**[7] **A61K 31/44**

(52) **U.S. Cl.** **514/338**

(58) **Field of Search** 514/338

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,128,658	A	12/1978	Price et al.	424/285
4,255,431	A	3/1981	Junggren et al.	424/263
4,279,819	A	7/1981	Price et al.	260/326.5 S
4,337,257	A	6/1982	Junggren et al.	424/263
4,508,905	A	4/1985	Junggren et al.	546/271
4,555,518	A	11/1985	Rainer	514/338
4,596,795	A	6/1986	Pitha	514/58
4,612,378	A	9/1986	Bosshard et al.	548/170
4,620,008	A	10/1986	Bräändström et al.	546/271
4,628,098	A	12/1986	Nohara et al.	564/271
4,636,499	A	1/1987	Brändström et al.	514/222
4,725,691	A	2/1988	Brändström et al.	546/172
4,727,064	A	2/1988	Pitha	514/58
4,738,974	A	4/1988	Brändström	514/338
4,753,955	A	6/1988	Matsuishi et al.	514/338
4,772,619	A	9/1988	Adelstein et al.	514/338
4,777,172	A	10/1988	Ife et al.	514/234.5
4,786,505	A	11/1988	Lovgren et al.	424/468
4,808,596	A	2/1989	Matsuishi et al.	514/303
4,820,708	A	4/1989	Ife et al.	514/232.8
4,840,799	A	6/1989	Appelgren et al.	424/493
4,853,230	A	8/1989	Lovgren et al.	424/466
5,021,443	A	6/1991	Bru-Magniez et al.	514/394
5,045,321	A	9/1991	Makino et al.	424/475
5,070,101	A	12/1991	Kaminski	514/399
5,075,323	A	12/1991	Fain et al.	514/338
5,093,132	A	3/1992	Makino et al.	424/475
5,093,342	A	3/1992	Tomoi et al.	514/328
5,096,893	A	3/1992	Pitha et al.	514/58
5,106,863	A	4/1992	Hajos et al.	514/395

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

DE	4035455	A1	5/1992	C07D/401/12
EP	0124495	A2	11/1984	C07D/401/12
EP	0166287	B1	1/1986	C07D/401/12
EP	0171372	A1	2/1986	C07D/513/14
EP	0197013	A1	10/1986	C07D/401/12
EP	0484265	A1	5/1992	C07D/401/12
EP	0585722	A1	3/1994	A61K/31/44
JP	61007281	A2	1/1986	C07D/513/14
JP	61205211		9/1986	A61K/31/44
JP	61271259		12/1986	C07C/93/14

(List continued on next page.)

OTHER PUBLICATIONS

"The Mechanism of Action of the Gastric Acid Secretion Inhibitor Omeprazole," *Journal of Medicinal Chemistry* 29:8 1327–1329 (1986).

Beckett et al.; "4–Hydroxybenzazoles: Preparation and Antibacterial Activities," *J. Pharm. and Pharmacol* 8:661–665 (1956).

Brändström et al.; "Structure activity relationships of substituted benzimidazoles," *Scandinavian Journal of Gastroenterology* 20:Supplemental 108 15–22 (1985).

Brändström et al.; "Chemical Reactions of Omeprazole and Omeprazole Analogues. I. A Survey of the Chemical Transformations of Omeprazole and its Analogues," *Acta Chemica Scandinavica* 43:536–548 (1989).

Brändström et al.; "Chemical Reactions of Omeprazole and Omeprazole Analogues. II. Kinetics of the Reaction of Omeprazole in the Presence of 2–Mercaptoethanol," *Acta Chemica Scandinavica* 43:549–568 (1989).

Brändström et al.; "Chemical Reactions of Omeprazole and Omeprazole Analogues. III. Protolytic Behaviour of Compounds in the Omeprazole System," *Acta Chemica Scandinavica* 43:569–576 (1989).

(List continued on next page.)

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(57) **ABSTRACT**

Compounds represented by formula (Ia) are disclosed by the invention, along with compositions and complexes thereof, optionally in combination with compounds of formula (Ib). Pharmaceutical formulations and methods of making and using such compounds are also disclosed.

30 Claims, No Drawings

U.S. PATENT DOCUMENTS

5,124,158	A	6/1992	Ruwart et al.	424/449
5,178,867	A	1/1993	Guittard et al.	424/473
5,196,205	A	3/1993	Borody	424/653
5,204,118	A	4/1993	Goldman et al.	424/489
5,206,025	A	4/1993	Courteille et al.	424/439
5,219,870	A	6/1993	Kim	514/338
5,232,706	A	8/1993	Palomo Coll	424/475
5,244,670	A	9/1993	Upson et al.	424/439
5,246,714	A	9/1993	Dahlinder et al.	424/497
5,288,506	A	2/1994	Spickett et al.	424/498
5,294,439	A	3/1994	Yamasaka et al.	424/78.01
5,294,629	A	3/1994	Machinami et al.	514/366
5,304,540	A	4/1994	Blackburn et al.	514/2
5,352,688	A	10/1994	Kaminski	514/357
5,362,424	A	11/1994	Lee et al.	264/4.3
5,374,730	A	12/1994	Stemon et al.	546/271
5,385,739	A	1/1995	Debregeas et al.	424/494
5,386,032	A	1/1995	Brändström	546/271
5,391,752	A	2/1995	Hoerner et al.	546/271
5,399,700	A	3/1995	Min et al.	546/271
5,417,980	A	5/1995	Goldman et al.	424/464
5,433,959	A	7/1995	Makino et al.	424/475
5,476,669	A	12/1995	Borody	424/653
5,508,041	A	4/1996	Lee et al.	424/451
5,514,660	A	5/1996	Zopf et al.	514/25
5,518,730	A	5/1996	Fuisz	424/426
5,536,735	A	7/1996	Takechi et al.	514/338
5,571,811	A	11/1996	Heeres et al.	514/252
5,578,732	A	11/1996	Kato et al.	546/273.7
5,582,837	A	12/1996	Shell	424/451
5,589,491	A	12/1996	Nakanishi et al.	514/338
5,599,794	A	2/1997	Eek et al.	514/29
5,616,593	A	4/1997	Patel et al.	514/321
5,620,964	A	4/1997	Roth et al.	514/53
5,622,717	A	4/1997	Fuisz	424/488
5,629,305	A	5/1997	Eek et al.	514/199
5,633,244	A	5/1997	Eek et al.	514/199
5,635,520	A	6/1997	Uda	514/338
5,637,592	A	6/1997	Heeres et al.	514/252
5,639,478	A	6/1997	Makino et al.	424/475
5,639,754	A	6/1997	Heeres et al.	514/252
5,650,411	A	7/1997	Heeres et al.	514/252
5,651,987	A	7/1997	Fuisz	424/488
5,656,286	A	8/1997	Miranda et al.	424/449
5,665,730	A	9/1997	Senn-Bilfinger et al.	514/300
5,670,932	A	9/1997	Kizima	340/384.6
5,686,588	A	11/1997	Yoo	536/13.3
5,693,818	A	12/1997	Von Unge	546/273.7
5,710,156	A	1/1998	Heeres et al.	514/255
5,714,504	A	2/1998	Lindberg et al.	514/338
5,719,161	A	2/1998	Rainer	514/300
5,728,700	A	3/1998	Heeres et al.	514/252
5,731,002	A	3/1998	Olovson et al.	424/484
5,753,630	A	5/1998	Zopf et al.	514/25
5,766,622	A	6/1998	Nelson	424/440
5,776,765	A	7/1998	Graham et al.	435/280
5,811,426	A	9/1998	Heeres et al.	514/252
5,811,547	A	9/1998	Nakamichi et al.	540/589
5,817,338	A	10/1998	Bergstrand et al.	424/468
5,840,552	A	11/1998	Holt et al.	435/118
5,846,562	A	12/1998	Yanai et al.	424/451
5,859,030	A	1/1999	Kohl et al.	514/338
5,877,192	A	3/1999	Lindberg et al.	514/338
5,916,904	A	6/1999	Sato et al.	514/338
5,929,244	A	7/1999	Von Unge	546/273.7
5,948,789	A	9/1999	Larsson et al.	514/299
6,262,085	B1	7/2001	Whittle et al.	514/338
6,262,086	B1	7/2001	Whittle et al.	514/338
6,268,385	B1	7/2001	Whittle et al.	514/338

FOREIGN PATENT DOCUMENTS

JP	02049774 A2	2/1990	C07D/235/28
JP	06096581	4/1994	G11C/114/01
JP	06316573	11/1994	C07D/401/12
WO	WO 89/03829	5/1989	C07D/401/12
WO	WO 92/08716	5/1992	C07D/401/12
WO	WO 93/21920	11/1993	A61K/31/44
WO	WO 94/02141	2/1994	A61K/31/44
WO	WO 94/27988	12/1994	C07D/401/12
WO	WO 95/01783	1/1995	A61K/9/24
WO	WO 95/01977	1/1995	C07D/401/12
WO	WO 95/18612	7/1995	A61K/31/44
WO	WO 95/32957	12/1995	C07D/401/12
WO	WO96/01622	1/1996	A61K/9/24
WO	WO 96/01623	1/1996	A61K/9/26
WO	WO 96/02535	2/1997	C07D/401/12
WO	WO 97/20851	6/1997	C07F/7/08
WO	WO 97/25030	7/1997	A61K/9/46
WO	WO 98/19668	5/1998	A61K/9/50
WO	WO 98/53803	12/1998	A61K/9/28
WO	WO 98/54171	12/1998	C07D/401/12
WO	WO 99/08500	2/1999	

OTHER PUBLICATIONS

Brändström et al.; "Chemical Reactions of Omeprazole and Omeprazole Analogues. IV. Reactions of Compounds of the Omeprazole System with 2–Mercaptoethanol," *Acta Chemica Scandinavica* 43:577–586 (1989).

Brändström et al.; "Chemical Reactions of Omeprazole and Omeprazole Analogues. V. The Reaction of N–Alkylated Derivatives of Omeprazole Analogues with 2–Mercaptoethanol," *Acta Chemica Scandinavica* 43:587–594 (1989).

Brändström et al.; "Chemical Reactions of Omeprazole and Omeprazole Analogues. VI. The Reactions of Omeprazole in the Absence of 2–Mercaptoethanol," *Acta Chemica Scandinavica* 43:595–611 (1989).

Clissold et al.; "Omeprazole A Preliminary Review of its Pharmacodynamic and Pharmacokinetic Properties, and Therapeutic Potential in Peptic Ulcer Disease and Zollinger–Ellison Syndrome," *Drugs* 32:15–47 (1986).

Erlandsson; "Resolution of the enantiomers of omeprazole and some of its analogues by liquid chromatography on a trisphenylcarbomoylcellulose–based stationary phase. The effect of the enantiomers of omeprazole on gastric glands," *Journal of Chromatography* 532:305–319 (1990).

Lindberg et al.; "Structure–activity relationships of omeprazole analogues and their mechanism of action," *TIPS* 8:399–402 (Oct. 1987).

Maier et al.; "Diphenylethanediamine (DPEDA) Derivatives as Chiral Selectors: IV. A Comparison of 3,5–Dinitrobenzoylated (S,S)– and (S,R)–DPEDA–Derived Chiral Stationary Phases with Pirkle's Standard (R)–Phenylglycine–Derived Phase in Normal Phase HPLC," *Chirality* 6:116–128 (1994).

Marle et al.; "Separation of enantiomers using cellulase (CBH I) silica as a chiral stationary phase," *Journal of Chromatography* 582:233–248 (1991).

Marle et al.; "Chiral stationary phases based on intact and fragmented cellobiohydrolase I immobilized on silica," *Journal of Chromatography* 648:333–347 (1993).

Ohishi et al.; "Structure of 5–Methoxy–2–{[4–methoxy–3, 5–dimethyl–2–pyridinyl)methyl] sulfinyl}–1H–benzimidazole (Omeprazole)," *Acta Cryst.* C45:1921–1923 (1989).

Sachs et al.; "Gastric H,K–ATPase as Therapeutic Target," *Ann. Rev. Pharmacol. Toxicol.* 28:269–284 (1988).

Uray et al.; "Diphenylethanediamine derivatives as chiral selectors VIII. Influence of the second amido function on the high–performance liquid chromatographic enantioseparation characteristics of (N–3,5–dinitrobenzoyl)–diphenylethanediamine based chiral stationary phases," *Journal of Chromatography A* 799:1+2 67–81 (Mar. 1998).

von Unge et al.; "Stereochemical assignment of the enantiomers of omeprazole from X–ray analysis of a fenchyloxymethyl derivative of (+)–(R)–omeprazole," *Tetrahedron: Asymmetry* 8:12 1967–1970 (1997).

U.S. patent application No. 09/629,587 to Whittle, et al. entitled *Pharmaceutical Formulations*; filed Jul. 31, 2000.

U.S. patent application No. 09/628,840 to Whittle, et al. entitled *Method of Improving Bioavailability*; filed Jul. 31, 2000.

U.S. patent application No. 09/629,634 to Whittle, et al. entitled *Pharmaceutical Unit Dosage Form*; filed Jul. 31, 2000.

U.S. patent application No. 09/645,148 to Whittle, et al. entitled *Dry Blend Pharmaceutical Unit Dosage Form*; filed Aug. 24, 2000.